Remarks

Claim 16 has been amended. New claims 35-40 have been added. Support for the amendment to claim 16 and new claims 35-40 can be found in general throughout Applicants' Specification and in particular, for example, as follows: claims 16 and 35, previously pending claim 2, claim 36, page 3, lines 4-5, claim 37, page 7, lines 10-12, claim 38, page 8, lines 4-5, claim 39, page 9, lines 5-7, claim 40, page 3, lines 8-11. No new matter has been added. Applicants reserve the right to prosecute the claims in their original form in a continuing application.

Applicants thank the Examiner for kindly indicating that claim 2 would be allowable if rewritten in independent form. Applicants have done this in the form of new claim 35. Applicants also thank the Examiner for withdrawing the previous rejections of record.

Rejections under 35 U.S.C. § 103

A. Claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 stand rejected under 35 U.S.C. § 103 over Brennan (AU 200157788) in view of Lieberman et al. eds. (Mohrle, Raymond, "Effervescent Tablets," *Pharmaceutical Dosage Forms: Tablets*, Second Edition, volume 1, New York: Marcel Dekker, Inc., 1989, pp. 285-303), hereinafter referred to as "Lieberman."

Brennan discloses a method of manufacturing effervescent tablets in which the tablets can be manufactured in a normal or ambient environment to allegedly produce tablets that are less affected by atmospheric humidity (Brennan, page 2, lines 4-7). Brennan further discloses including cranberry extract, glucosamine or ubidecarenone in his tablets (*Id.*, lines 14-16).

Lieberman discusses effervescent tablet technology in general including formulation, manufacture and disintegration of effervescent tablets. Lieberman discloses, "[i]f the tablet components are not soluble, the effervescent reaction will not occur and the tablet will not disintegrate quickly" (Lieberman, page 287). Lieberman further discloses that "[t]he rate of solubility is perhaps even more important than solubility per se since a slowly dissolving soluble substance can hinder tablet disintegration and provide a slowly soluble, often objectionable residue after the tablet disintegrates" (*Id*).

Lieberman also discloses that the use of a binder is limited because binders will retard the disintegration of an effervescent tablet (*Id.*, page 291). Lieberman then discloses,

> Many substances are effective lubricants in certain concentrations but inhibit tablet disintegration at these same concentrations. When the concentration is lowered to permit the tablet to properly disintegrate, the lubricating efficiency of the material is lost or so greatly diminished that it is no longer useful. If a clear solution is desired when the tablet disintegrates, the problem is even greater since the most efficient lubricants are water-insoluble and will leave a cloudy solution once dispersed.

(*Id.*, page 292).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent comprising an acid and a base, binder, and lubricant, the tablet disintegrating in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. It is undisputed that Brennan does not expressly teach the tablet of claim 1. Applicants have also demonstrated that Brennan does not inherently teach the tablet of claim 1 by demonstrating that the cranberry extract tablet example of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. (See, March 13, 2009 Amendment and Declaration of Kyle M Johnson, which is attached thereto.)

Lieberman does not teach how to formulate the tablet of claim 1. Lieberman provides general concepts. However, he does not expressly direct the skilled artisan to select any particular ingredients for inclusion in a composition that also includes cranberry extract. Lieberman further fails to teach the skilled artisan how to go about selecting ingredients to achieve an effervescent tablet that includes at least 200 mg cranberry extract and disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. Lieberman's discussion about binders does not cure this defect. Lieberman discloses:

> The use of any binder, even one that is water-soluble, <u>will retard the disintegration</u> of an effervescent tablet. In granulations that require a binder for

> tableting, a proper balance must be chosen between granule cohesiveness and desired tablet disintegration.

(Lieberman, page 291). (Emphasis added.) Therefore, Lieberman discloses that the presence of binder in an effervescent tablet retards the disintegration of the tablet, but he does not teach how to select an appropriate binder or how much binder to use. He further fails to teach that a specific binder and amount thereof will produce a particular with respect to disintegration time. His words do, however, inform the skilled artisan that increasing the amount of binder will increase the rate of disintegration of the tablet. Applicants have already demonstrated that the tablet of the example of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Lieberman does not direct the skilled artisan how to modify the composition of Brennan so as to achieve a composition that will form a tablet and will disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Brennan does not disclose which binder should be used or how much of it should be used. When Applicants attempted to prepare the Brennan cranberry extract tablet, they had difficulty achieving a tablet that did not cap at a lower hardness (See, Declaration of Kyle M. Johnson). To achieve a tablet that did not cap, the tablet was made harder (*Id.*). In general, harder tablets take longer to disintegrate than softer tablets (See, Mr. Johnson's Declaration, para. 9). The skilled artisan would have to conduct a number of experiments and use trial and error in an attempt to achieve a tablet that exhibits the properties of claim 1. As such, Lieberman does not render obvious the composition of claim 1.

The disclosure of Lieberman is at most a starting point: a jumping off point. It does not provide the requisite direction to the skilled artisan that would enable the skilled artisan to arrive at the tablet of claim 1. It has been established that an invention would not have been obvious to try when an inventor would have had to try all possibilities in a field unreduced by direction of the prior art. "When what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *Bayer Sherman Pharma AG v. Barr Laboratories, Inc.*, _____ F.3d _____ (Fed. Cir. 2009)

quoting O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). This is another way to express the requirement issued by the United States Supreme Court in *KSR* that the field of search to be among a "finite number of identified" solutions. *Bayer v. Barr, quoting KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007); see also *Procter & Gamble Co. v Teva Pharms. USA, Inc.*, 566 F.3d 989, 996 (Fed. Cir. 2009). As explained above, here, the skilled artisan would have had to vary many parameters and select from numerous possible choices. Therefore, the proposed combination of Brennan and Lieberman does not enable the skilled artisan to make the tablet of claim 1. As such, the proposed combination of Brennan and Lieberman cannot render obvious the tablet of claim 1. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Brennan in view of Lieberman cannot stand and respectfully request that it be withdrawn.

Claims 3-5, 8-10, 13, 15, 18, and 32-34 depend either directly or indirectly from claim 1 and are distinguishable under 35 U.S.C. § 103 over Brennan in view of Lieberman for at least the same reasons set forth above in distinguishing claim 1.

Claim 33 depends from claim 1 and specifies that the tablet has a hardness of at least 5 kiloponds. Neither Brennan nor Lieberman teaches or suggests how to achieve a tablet a hardness of at least 5 kiloponds and disintegrating in water having a temperature of about 22°C in less than 2.5 minutes. Therefore the proposed combination of Brennan and Lieberman fails to enable the tablet of claim 33. For at least this additional reason the rejection of claim 33 under 35 U.S.C. § 103 over Brennan in view of Lieberman is unwarranted, and Applicants respectfully request that it be withdrawn.

Claim 31 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder, and lubricant, the binder being present in the composition in amount of from about 15 % by weight to about 50 % by weight, the tablet being free of picking, capping, die wall etching and lamination, having a hardness of at least 3 kiloponds, and disintegrating in water having a temperature of about 22°C in less than 2.5 minutes. Applicants have established that Brennan does not expressly or inherently teach a tablet that disintegrates in water having a temperature of about 22°C in

less than 2.5 minutes (see March 13th Amendment). Brennan further fails to teach or suggest how to achieve such a tablet.

Brennan is further deficient in that he does not teach or suggest how much binder should be included in an effervescent tablet that includes cranberry extract. The cranberry extract tablet example includes polyvinylpyrrolidone and polyethylene glycol, both of which can act as binders in an effervescent tablet. The combined amount of polyvinylpyrrolidone and polyethylene glycol in Brennan's tablet is 100 mg and the tablet weight is 4000 mg, which means that at most the Brennan cranberry extract tablet includes 2.5 % by weight binder. Brennan does not teach or suggest including from about 15 % by weight to about 50 % by weight binder in a cranberry extract effervescent tablet.

Lieberman does not cure the deficiencies of Brennan. Lieberman provides, at most, a starting point. He does not direct the skilled artisan how to select among the various components including, e.g., acids, bases, lubricants, binders, and sweeteners, or how to determine the appropriate amounts thereof to arrive at a tablet that includes cranberry extract, has a hardness of at least 3 kiloponds, and disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Lieberman also does not teach or suggest that it is predictable that the use of any one component or combination of components or that a particular amount of a component or combination of components will result in a tablet having any particular disintegration rate or hardness. Nothing in Lieberman teaches or suggests that forming effervescent tablets is a predictable art. Therefore, the skilled artisan in possession of Lieberman would have to vary a number of parameters and try each of numerous possible choices until he or she possibly arrived at a successful result. Under such circumstances, it has been determined that an invention is not obvious. See, e.g., *Bayer Sherman Pharma AG v. Barr Laboratories, Inc.*, _____ F.3d _____ (Fed. Cir. 2009). Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Brennan in view of Lieberman has been overcome and respectfully request that it be withdrawn.

B. Claims 5-9 stand rejected under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Usukura (JP 2001-342142).

The disclosure of Brennan and Lieberman as summarized above is incorporated herein by reference.

Usukura is directed to a composition that is alleged to improve the effects for urination abnormality and urinary incontinence cause by urinary tract infectious disease and prostate hypertrophy (*Id.*, Abstract). The composition includes cranberries or their extract and pumpkin seeds or their extract (*Id.*).

Since the rejection of claim 1 is based upon the premise that the proposed combination of Brennan in view of Lieberman renders obvious claim 1, and this premise has been refuted, the rejection of claim 5, which depends directly from claim 1, under 35 U.S.C. § 103 over Brennan in view of Lieberman likewise is unwarranted and cannot stand. The rejection of claim 5 is further unwarranted for at least the following additional reasons.

Claim 5 depends from claim 1 and further specifies that the tablet includes at least 500 mg cranberry extract. It is undisputed that Brennan does not teach including at least 500 mg cranberry extract in his effervescent tablet. Brennan also does not teach or suggest how to incorporate at least 500 mg cranberry extract into his effervescent composition such that an effervescent tablet made from the same will disintegrate in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles.

It is undisputed that Lieberman fails to mention anything about cranberry extract. Lieberman also does not teach or suggest how to include at least 500 mg cranberry extract in an effervescent tablet.

Usukura does not cure this deficiency. Usukura discloses, "[I]t is preferred to blend 100-5000-mg 50-10000 mg as an adult one-day dose into this invention constituent." Usukura, para. [0012]. Usukura does not teach anything about how to formulate an effervescent tablet. Usukura also does not teach or suggest how to incorporate at least 500 mg cranberry extract into an effervescent composition such that an effervescent tablet made from the same will disintegrate in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. Usukura also does not teach or suggest which components of the Brennan composition should be changed, increased or decreased to accommodate the increased

amount of cranberry extract. Usukura further fails to direct the skilled artisan how to select the other components of the Brennan composition so as to achieve an effervescent tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, at best the skilled artisan would have to launch into a series of trial and error experiments, in an art that is unpredictable and does not include a finite number of predictable solutions, in an attempt to achieve the tablet of claim 5. As has been established above, such circumstances do not and cannot render the tablet of claim 5 obvious.

Claims 6-9 are further distinguishable under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Usukura for at least the same reasons set forth above in distinguishing claim 5.

C. Claims 11 and 12 stand rejected under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Korab (US 4,704,269).

The disclosure of Brennan and Lieberman as summarized above is incorporated herein by reference.

Korab is directed to effervescent antacid and analgesic compositions.

The rejection of claims 11 and 12, which depend directly from claim 1, is based upon the premise that the proposed combination of Brennan in view of Lieberman renders obvious claim 1. Since this premise has been refuted, and the secondary reference of Korab does not cure the deficiencies of Brennan and Lieberman, the rejection of claims 11 and 12 under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Korab is likewise unwarranted and cannot stand.

D. Claim 14 stands rejected under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Mann (U.S. 2002/0102336).

The rejection of claim 14, which depend directly from claim 1, is based upon the premise that the proposed combination of Brennan in view of Lieberman renders obvious claim 1. Since this premise has been refuted, and the secondary reference of Mann does not cure the deficiencies of Brennan and Lieberman, the rejection of claim 14 under 35 U.S.C. § 103 over Brennan in view of Lieberman and further in view of Mann is likewise

unwarranted and cannot stand. The rejection of claim 14 is further deficient for at least the following additional reasons.

Brennan discloses a method of manufacturing effervescent tablets in which the tablets can be manufactured in a normal or ambient environment to allegedly produce tablets that are less affected by atmospheric humidity (Brennan, page 2, lines 4-7). Brennan further discloses including cranberry extract, glucosamine or ubidecarenone in his tablets (*Id.*, lines 14-16). Brennan discloses a cranberry fruit extract that is a twenty five fold concentrate, i.e., 25:1, of cranberry juice absorbed onto an inert solid, e.g., :maltodextrin.

The discussion of the Lieberman disclosure as set forth above is incorporated herein.

Mann discloses a method of stabilizing fruit concentrate (Mann, Abstract). The method includes blending the fruit with an aqueous solution that includes magnesium hydroxide, an organic acid component, and a stabilizer, and drying the fruit to produce a dried fruit powder (*Id.*, para. [0007]). Mann discloses that his process yields between 85 % and 95 % solids in the final product depending on the dried fruit (*Id.*, para. [0013]).

Claim 14 depends from claim 1 and specifies that the tablet further includes magnesium hydroxide. Mann indicates that it is undesirable to include magnesium in compositions and that it is desirable to minimize the amount of magnesium (see, Mann, paras. [0005], [0011] and [0012]). Mann discloses that his process yields a product that includes from 91 % and 94 % fruit solids (*Id.*, para. [0014]). Mann does not expressly teach what fruit solids yield can be achieved for cranberry fruit juice. However, assuming for the sake of argument that a maximum yield of 94 % fruit solids (Applicants do not agree that Mann actually teaches such a yield for cranberry extract) is achieved, at best the Mann process yields a 15.7:1 ratio of cranberry juice concentrate to inert solid. The cranberry fruit extract of Brennan has a ratio of 25:1. The skilled artisan would have no reason to employ a product that provides less cranberry juice per gram of material than that provided by Brennan. Therefore, the skilled artisan would have no reason to use the product of Mann in the tablet of Brennan. Applicants submit, therefore, that the rejection of claim 14 under 35 U.S.C. § 103 over Brennan in view of Lieberman and

further in view of Mann is unwarranted for at least this additional reason and respectfully request that it be withdrawn.

E. Claim 16 stand rejected under 35 U.S.C. 103 over Nawar in view of Lieberman and any one of Takaichi (US 5,919,483), Alexander (US 4,783,331) and Schmitt (US 3,653,914).

Nawar discloses a cranberry seed oil extract and components thereof that are suitable for use as a foodstuff, dietary supplement or pharmaceutical composition (see, Nawar, Abstract). Nawar further discloses a method for extracting cranberry seed oil from cranberry seeds (Nawar, col. 2, ll. 27-35). Nawar also describes providing a compound derived from cranberry seed oil such as a cranberry seed oil extract that is substantially free of impurities. Nawar explains that his extract can include a long list of components including flavonoids (e.g., isoflavone), fatty acids, sterols and tocopherols (*Id.*, col. 2, ll. 38-52). Nawar also discloses that his cranberry seed oil extracts can be formulated as a pharmaceutical composition or a dietary supplement, added to various foodstuffs, or used in cosmetics (*Id.*, col. 18, ll. 35-65). Nawar further discloses that the pharmaceutical compositions may take the form of tablets, capsules, emulsions, suspensions and powders for oral administration, sterile solutions or emulsions for parenteral administration, sterile solutions for intravenous administration and gels, lotions and crèmes for topical application (*Id.*, col. 18, ll. 55-65).

Lieberman discloses that when tableting equipment was developed, granular materials began to be compressed into tablets that offer some advantages over powdered dosage forms (Lieberman, page 285). According to Lieberman, effervescent tablets are convenient, easy-to-use, premeasured dosage forms. (*Id.*) Lieberman notes that they cannot spill as can the powdered preparations and they can be individually packaged to exclude moisture, thereby avoiding the problem of product instability of the unused contents during storage. (*Id.*)

Lieberman also discloses that lubricants are one of the most important compounds in an effervescent tablet, that effervescent granulations are inherently difficult to lubricate, and that many substances are effective lubricants but inhibit tablet disintegration. (*Id.* at page 292) Lieberman further discloses that if a clear solution is

desired when the tablet disintegrates, the problem is even greater since the most efficient lubricants are water-insoluble and will leave a cloudy solution once dispersed.(*Id.*)

Takaichi discloses antioxidant-containing effervescent compositions (Takaichi, Abstract).

Alexander discloses methods for the solubilization of aspartame in effervescent aqueous systems.

Schmitt describes producing tablets.

Claim 16 is directed to an effervescent tablet comprising an effervescent composition that includes from 50 mg to 200 mg cranberry seed oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 5 kiloponds and disintegrating in water having a temperature of about 22°C less than 2.5 minutes. Nawar discloses that cranberry seed oil extacts can be administered in any suitable form including being added to food stuffs, formulated as pharmaceutical compositions, and formulated as dietary supplements (Nawar, col. 18, ll. 36-65). Nawar also discloses a long list of forms that pharmaceutical compositions may take including, e.g., tablets, capsules, emulsions, suspensions and powders for oral administration, sterile solutions or emulsions for parenteral administration, sterile solutions for intravenous administration and gels, lotions and crèmes for topical application (*Id.*, ll. 55-65). Nawar does not teach or suggest effervescent compositions, effervescent tablets or including cranberry seed oil in an effervescent composition or an effervescent tablet. The July 10th Office action does not dispute this fact.

Lieberman does not teach or suggest anything about cranberry seed oil. In particular, Lieberman does not teach or suggest formulating cranberry seed oil in an effervescent composition. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 418. Rather, to establish a *prima facie* case of obviousness based upon a proposed combination of references there must be a reason in the prior art to combine the references. See, *Id.* Evidence of a reason to combine can be found if there is a teaching, suggestion or motivation in the prior art for making the proposed combination. See, M.P.E.P. 2142; *Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d 1437 (Fed. Cir. 1997); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d

1340, 1352, (Fed. Cir. 1998). The reason, teaching, suggestion or motivation to make the claimed combination must be found in the prior art and must not be based on Appellants' disclosure. See, M.P.E.P. 2142. Here there is no such reason, teaching, suggestion or motivation.

The July 10th Office action takes the position that the reason lies in the disclosure by Lieberman. The July 10th Office action mischaracterizes the nature of that disclosure in two aspects. In the first aspect, the July 10th Office action asserts that Lieberman "teaches that effervescent tablets are superior dosage forms because they are convenient, easy-to-use, premeasured[,] and can be individually packaged to avoid product instability." July 10, 2009, Office action, page 7, lines 4-6. (Emphasis added.) Lieberman does not teach or suggest that effervescent tablets are "superior" dosage forms. Rather, Lieberman states:

> When tableting equipment was developed, these granular materials began to be compressed into tablets that offer some advantages over the powdered dosage forms. Effervescent tablets are convenient, easy-to-use, premeasured dosage forms. They cannot spill as can the powdered preparations. They can be individually packaged to exclude moisture, thereby avoiding the problem of product instability of the unused contents during storage.

Lieberman, page 285, first paragraph. In other words, Lieberman disclose the benefits of tablets over powdered dosage forms. Lieberman does not teach or suggest that effervescent tablets are superior to any dosage form. Moreover, Lieberman is specific to identifying advantages effervescent tablets have over powdered preparations. Lieberman does not teach or suggest that effervescent tablets have advantages over any other dosage form. It is particularly noteworthy that many other dosage forms exhibit the properties Lieberman mentions above including, e.g., non-effervescent tablets, capsules, gel tabs, and gums, and gels, lotions and crèmes for topical application.

In the second aspect, the July 10th Office action incorrectly asserts that Lieberman teaches that formulating a composition as an effervescent tablet will increase the bioavailability of all pharmaceutical compounds. This is not true. Lieberman discloses that some studies indicate that that there are significant differences in absorption kinetics of aspirin, and some studies indicate that no significant differences were observed

(Lieberman, page 286, para. 2). Lieberman also discloses that in one study an investigator reported increased bioavailabilty of phenylbutazone from an effervescent dosage form (*Id.*). Nothing in this passage can be read to constitute a teaching that effervescent tablets increase the bioavailability of all pharmaceutical compositions, and Lieberman does not teach or suggest that effervescent dosage forms actually increase bioavailability or that they do so for each and every compound known to mankind. Moreover, in the instance of the one reported increase, Lieberman does not teach or suggest to what the increase was relative. Therefore, nothing in Lieberman provides the requisite teaching, reason, motivation or suggestion to the skilled artisan to formulate the cranberry oil as an effervescent composition –let alone an effervescent tablet. Therefore the skilled artisan would not even think to do so and further would have absolutely reasonable expectation that cranberry oil, in particular, would be improved by formulating it as an effervescent composition –let alone an effervescent tablet.

It is further noteworthy that many dosage forms exist. There are not a finite number of dosage forms and there is no direction in either Nawar or Lieberman that indicates that a successful effervescent tablet could be formed using cranberry seed oil. There is also nothing in either Nawar or Lieberman that specifically directs the skilled artisan to select an effervescent tablet for delivering cranberry seed oil.

The July 10th Office action further asserts that Lieberman "teaches that when oils are incorporated into effervescent tablets, the oils should be included in a concentration of 1 % or less" (July 10th Office action, page 8). This is not true. Lieberman actually states,

> The magnesium, calcium and zinc salts of stearic acid are the most efficient substances commonly used. Concentrations if 1 % or less are usually effective; however, they are not water soluble, can hinder tablet disintegration, and produce cloudy solutions.

(Lieberman, page 292, para. 3.) Nothing in the above-quoted passage constitutes a generic teaching about oils or the amount of oil that should be included in an effervescent tablet. To the contrary, it is specific to the lubricants mentioned therein and further discloses what is "usually effective," i.e., for lubrication purposes. Nothing in this passage refers to either active agents, pharmaceuticals, or fruit oil extracts. Therefore,

the skilled artisan would find this passage to have no bearing on cranberry seed oil, and further would find that it provides no reason to include cranberry seed oil in an effervescent tablet, let alone to include from 50 mg to 200 mg cranberry oil in an effervescent tablet. The skilled artisan thus would have no reason to do so.

Lieberman further fail to teach the skilled artisan how to select from among the numerous possible ingredients, and the amounts thereof, so as to arrive at an effervescent tablet that includes from 50 mg to 200 mg cranberry seed oil and that has a hardness of at least 5 kiloponds and disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Therefore the proposed combination of Nawar and Lieberman fails to enable the tablet of claim 16.

It is undisputed that the tertiary references of Takaichi, Alexander and Schmitt fail to cure the deficiencies of the proposed combination of Nawar and Lieberman. The July 10th Office action takes the position that because Takaichi, Alexander and Schmitt allegedly disclose effervescent tablets that weigh between 5,000 mg and 5,780 mg, the skilled artisan would include from 50 mg and 57.8 mg of cranberry seed oil in an effervescent tablet. Applicants disagree with these statements and conclusions. As a preliminary matter, Applicants have already demonstrated that Lieberman does not teach or suggest including 1 % by weight oil in an effervescent composition –let alone including 1 % by weight oil of an active agent in the form of an oil in an effervescent composition. Furthermore, neither Takaichi nor Alexander nor Schmitt teaches or suggests or provides a reason for including from 50 mg and 57.8 mg of any oil in their composition --let alone cranberry seed oil. Therefore, the proposed combination of references fails to teach a required element of the tablet of claim 16, i.e., from 50 mg to 200 mg cranberry seed oil. Nothing in the record establishes anything to the contrary. As such, a *prima facie* case of obviousness of claim 16 has not been made. Moreover, because there is no such teaching, the skilled artisan would have no reason to *sua sponte* from 50 mg to 200 mg cranberry seed oil in an effervescent tablet. Thus, the rejection of claim 16 under 35 U.S.C. § 103 over Nawar in view of Lieberman and further in view of any one of Takaichi, Alexander or Schmitt cannot stand, and Applicants respectfully request that it be withdrawn.

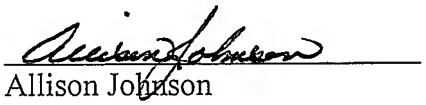
Any statements contained in the July 10th Office action not expressly addressed herein are hereby expressly traversed.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of this application.

Please charge any additional fees that may be required or credit any overpayment made to Deposit Account No. 501,171.

Respectfully submitted,

Date: October 9, 2009



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